Remarks

Summary of Amendments

The specification has been amended in response to a requirement. The claims have been amended for better compliance with 35 USC 112. The terms "free" added to claim 9 and "unbound" added to claim 14 are submitted to be fairly supported overall by the specification as filed, for example, page 5 line 4 and page 8 line 16. The amendments to claim 15 are submitted to be fairly supported by the three paragraphs beginning at page 8, line 24. Support for the other amendments is believed self evident. No new matter is presented.

Status of claims

Claims 1-18 are pending. Numerous restriction and election of species requirements have been made and previously responded to. Claims 1-8 stand withdrawn from consideration. Claims 9-18 stand provisionally elected. In claims 9-18, IgE stands provisionally elected as the species of serum protein to be reduced and SEQ ID No: 1 stands provisionally elected as the species of peptide to be administered. Diabetes stands provisionally elected as the species of IgE-mediated disease to be treated, this requirement having been traversed in the previous response and repeated and made final in the instant office action.

Amendment to the specification

The requirement made to submit a replacement paragraph incorporating the pen and ink changes in the specification as filed is complied with. No new matter is presented. Acceptance is requested.

Claim Objections

Claims 9 and 10 stand objected to because of the use of the term "containing" or a variant thereof in relation to amino acid sequences. The objection is traversed but is obviated by the above amendment in which the word "comprises" or a variant thereof is substituted therefor.

Reconsideration is requested.

Claim Rejections

Claims 17 and 18 stand rejected under 35 USC 112, second paragraph, as being incomplete for omitting essential steps. The rejection is traversed but is obviated by amendment of the claim 17 to delete reference to a diagnosing step and to recite "wherein said human further has" similar to claim 15. Reconsideration is requested.

Claims 9-18 stand rejected under 35 USC 112, first paragraph, for failure to comply with the enablement requirement. This rejection is traversed but is submitted to be obviated by the present amendment.

In the first paragraph beginning on page 6 of the office action, it is asserted that it has not been satisfactorily shown that the peptide treatment will treat asthma, diabetes, depression and autoimmune disease. Claims 9-16 as amended require reducing free IgE in serum, and no longer mention these disease conditions. Claims 17-18 require reducing free IgE in serum in humans also afflicted with a disease condition, but do not recite any causation or effectiveness against the disease. The data in Tables I and II supports the proposition that humans having the recited disease conditions are also more likely to have elevated free IgE. This group of people would therefore be highly likely to benefit from free-IgE reduction. Because the claims as amended no longer require that the recited disease conditions per se be effectively treated, reconsideration and withdrawal of this aspect of the 35 USC 112 rejection is requested.

In the paragraph beginning at the bottom of page 6 of the office action, is is asserted that it has not shown that the invention reduces IgE levels. This aspect of the rejection is traversed, but is obviated that the above amendment of claim 9. As amended, claim 9 requires that the peptide be administered so as "to reduce serum level of <u>free</u> IgE." The rejected claims therefore no longer require that IgE levels be reduced. Peptide binding to reduce the amount of free IgE is all that is required, and this is fairly supported by the data. Reconsideration and withdrawal of this aspect of the 35 USC 112 rejection is therefore requested.

In the the paragraph beginning in the middle of page 7, it is asserted that the results shown have not been shown to be statistically valid, which would lead to an undue amount of experimentation to practice the invention. This aspect of the rejection is traversed, but is obviated by the above amendment to the claims. As amended, the claims are directed toward reducing free-IgE levels, rather than the treatment of a specific condition. Reconsideration is therefore requested.

In the paragraph beginning in the middle of page 8, claims 17 and 18 are rejected for reciting a diagnosing step prior to the treatment step. The rejection is traversed, but is obviated by amendment of claim 17 to avoid this recitation. As amended, claim 17 requires that the human having the elevated IgE further has one of the recited conditions. Reconsideration and withdrawal of this aspect of the 35 USC 112 rejection is therefore requested.

Information disclosure issue

Confirmation that the prior art developed in the corresponding PCT application, PCT/US03/01044 has been considered is requested.

Conclusion

In view of the foregoing, reconsideration and withdrawal of all grounds of objection and rejection and early notice of allowance is respectfully requested.

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